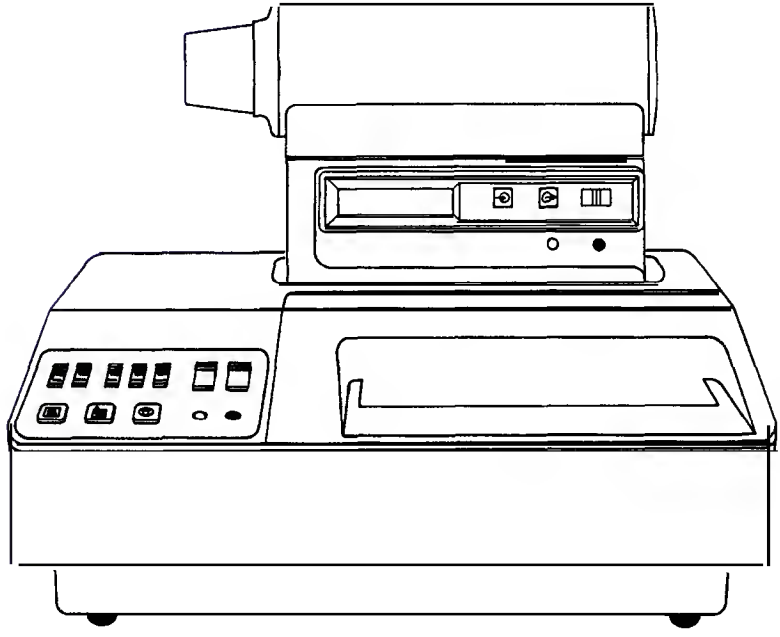
Welch Allyn

PneumoCheck™

and Printer/Charger Operating Instructions



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Thank you for purchasing the Welch Allyn PneumoCheck. The operating and maintenance instructions found in this manual should be followed to ensure many years of accurate and reliable service. Please read these instructions thoroughly before using your Welch Allyn PneumoCheck Spirometer and Printer/Charger.

**Welch Allyn gratefully acknowleges the assistance of Paul L. Enright, M.D. of the Mayo Clinic in Rochester, Minnesota for his assistance in preparing and reviewing sections of this manual.

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INTRODUCTION TO SPIROMETRY

The Welch Allyn PneumoCheck is a hand-held spirometer specifically designed to perform FVC and MVV spirometry tests easily and accurately. In order to properly use your PneumoCheck and to obtain useful test results, you should be familiar with the basic principles of spirometry:

A spirometer is a device that measures the amount of air that is breathed into or out of it.

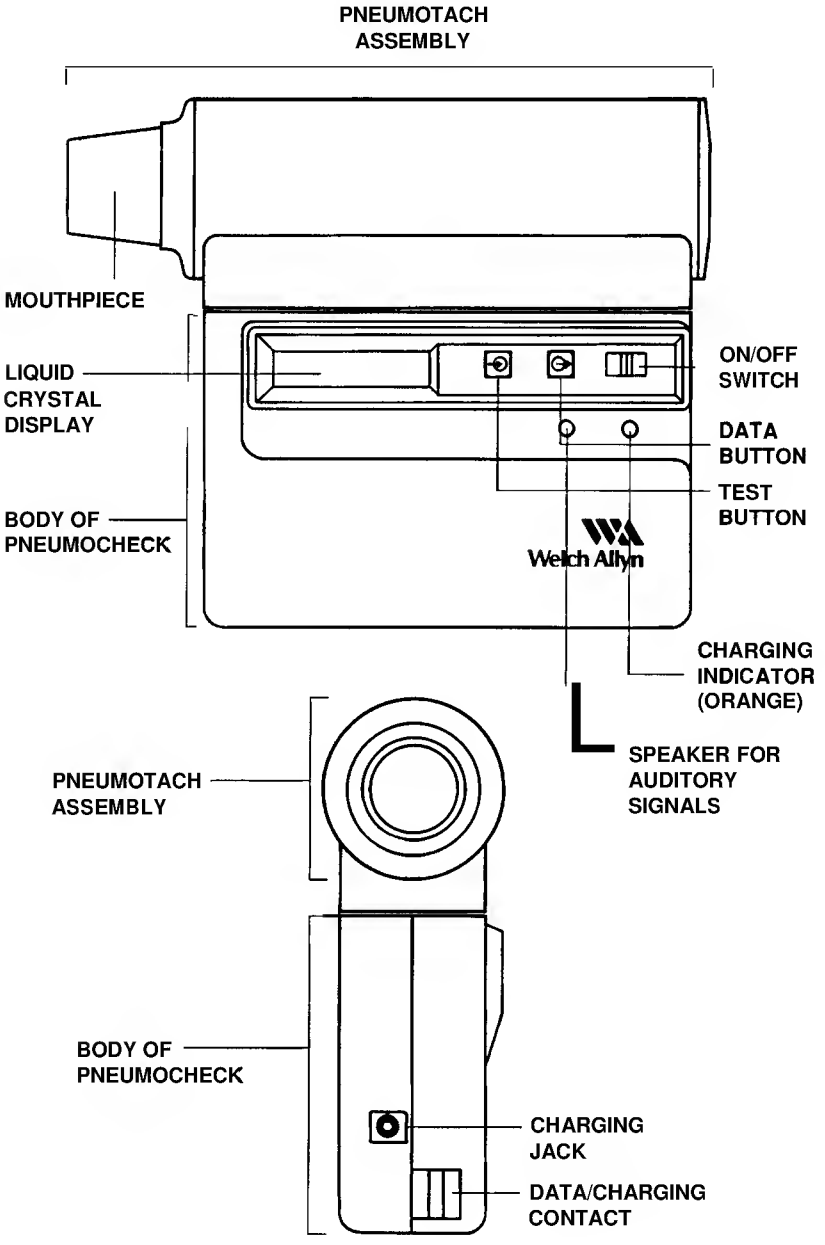
To perform a spirometry test, a patient breathes into the spirometer in a prescribed manner over a known period of time. Several different types of spirometry tests can be done using a spirometer, each of which yields different information about the patient's lung function.

INDICATIONS FOR SPIROMETRY

There are several well established, specific indications for office spirometry, including the following:

1. Yearly evaluation of smokers over 40 years old[1, 2].
2. Follow-up visits of all patients with asthma, bronchitis, emphysema, or other lung diseases[3].
3. Management of all patients on bronchodilators[3].
4. History of dyspnea with exertion or at rest[3].
5. History of chronic cough or sputum production[4].
6. History of wheezing or chest tightness[4].
7. History of frequent "colds" or allergic rhinitis[4].
8. Early detection of congestive heart failure[5, 6].
9. Preoperatively for all patients scheduled for thoracic or upper abdominal surgery[7].
10. Occupational exposure to inhaled dust or chemicals[8].
11. Documentation of pulmonary disability[9].
12. To evaluate the effects of environmental air pollution[10].

PARTS OF THE WELCH ALLYN PNEUMOCHECK SPIROMETER (#61000)



PRELIMINARY OPERATING INSTRUCTIONS

1. If the instrument has not been stored at room temperature, allow 45 minutes for the temperature of the instrument to stabilize.

2. Visually check the screen of the PneumoCheck (see p. 41) and check the calibration (see p. 31).

3. Instruct the patient about what is expected and how to perform a good test (see p. 8 for FVC or p. 21 for MVV).

4. Ask the adult patient to attach a disposable mouthpiece using a push-and-twist motion to ensure a snug fit.

   For children, insert a disposable pediatric mouthpiece.

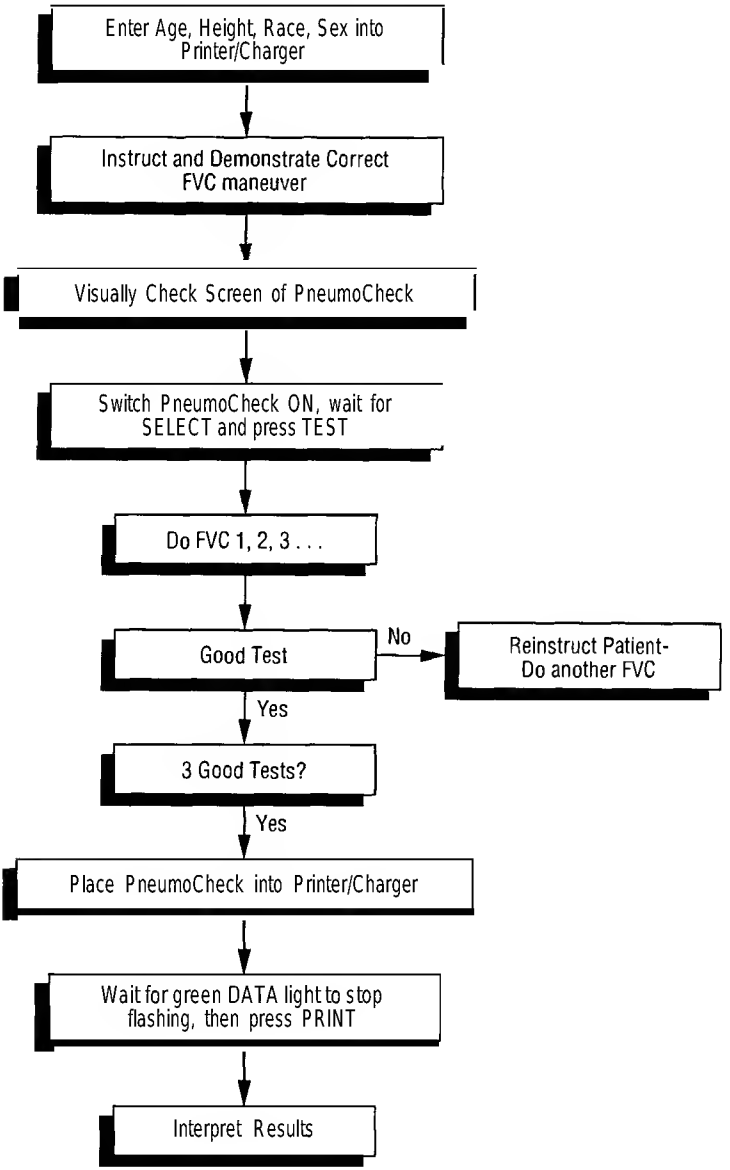
5. Slide the ON/OFF switch to the right to turn instrument on. The word CLEAR will appear on the liquid crystal display (LCD) and a beep will sound indicating the instrument's memory has been cleared.

6. When SELECT is displayed, select the type of test by repeatedly depressing the TEST button:

   Press once and release to access FVC.
   Press again and release for MVV.
   Press again and release for CAL (calibration).
   Press and release a fourth time to return to SELECT.

With each selection the appropriate word or abbreviation will appear on the liquid crystal display (SELECT, FVC, MVV, CAL). Within three seconds that particular test will begin.

QUICK FVC REFERENCE CHART
How To Use Your PneumoCheck and Printer/Charger


Enter Age, Height, Race, Sex into Printer/Charger
Instruct and Demonstrate Correct FVC maneuver
Visually Check Screen of PneumoCheck
Switch PneumoCheck ON, wait for SELECT and press TEST
Do FVC 1, 2, 3 . . .
Good Test
No
Reinstruct Patient- Do another FVC
Yes
3 Good Tests?
Yes
Place PneumoCheck into Printer/Charger
Wait for green DATA light to stop flashing, then press PRINT
Interpret Results

DESCRIPTION

The most frequently performed spirometry test is the forced expiratory vital capacity test, or FVC. It is commonly used for basic pulmonary function testing as well as managing patients with chronic obstructive pulmonary disease (COPD), asthma, emphysema, bronchitis, or other lung diseases.

When doing a single maneuver, the patient inhales as much air as possible, then exhales as rapidly and as completely as possible into the spirometer. To perform a complete FVC spirometry test, the patient should complete three or more acceptable FVC maneuvers with a brief rest between each one.

MEASUREMENT PARAMETERS

Several characteristics of the FVC maneuver are helpful in evaluating the patient's lung function.

The two most commonly used parameters are FVC and FEV1 :

FVC
Forced Expiratory Vital Capacity, the total amount of air (in liters) exhaled during an FVC maneuver.

FEVI
Forced Expiratory Volume in one second, the volume of air (in liters) exhaled during the first second of the FVC maneuver. FEVI is also the measure of the average flow rate during the first second of the FVC maneuver.

Other commonly used FVC parameters include:

FEVI /FVC%
(also called RATIO) the ratio of the FEV1 to the FVC, expressed as a percentage.

FEF25%-75%
Forced Expiratory Flow between the 25% and 75% volume points (also called Mean Mid Expiratory Flow or MMEF). A measurement of the average rate of flow (in liters/second) during the middle 50% of the FVC maneuver.

PEF
Peak Expiratory Flow, the highest rate of airflow (in liters/second) during the FVC maneuver.

Once an acceptable FVC maneuver has been completed, the test results can be compared to established norms and a course of action determined. The norms are based on the height, age, race and sex of the patient.

Lung disorders usually fall into one of two categories: obstructive lung diseases or restrictive disorders.

Obstructive lung diseases are those that cause a reduction in airflow rates or airflow limitation, such as asthma, chronic bronchitis, Chronic Obstructive Pulmonary Disease (COPD) and emphysema.

Restrictive disorders are those that cause the lung volume to be reduced, such as congestive heart failure with pulmonary edema, pneumonia, pleural fibrosis, pneumoconiosis and gross obesity.

In general, it is possible to categorize a lung disorder into one of these two groups and gauge its severity with a basic spirometry test, but it is usually not possible to identify the specific disorder without further information. The patient's respiratory history, work environment, response to various bronchodilators, and results from more specific pulmonary tests may be needed to fully diagnose the disorder.

NOTE: During FVC maneuvers in the normal operating mode, the instrument assumes that air at body temperature and pressure, fully saturated with water (BTPS) will be used, and a BTPS factor is applied.

OBTAINING GOOD FVC TEST RESULTS

Accuracy of spirometry testing is very dependent on the effort of the patient and is only valid if the patient cooperates and performs the test to the best of his/her ability. Properly instructing and coaching the patient throughout the maneuver is therefore critical.

Your Welch Allyn PneumoCheck has a sophisticated monitoring system which will help you in deciding whether a maneuver was a valid effort.

However, you must know how to properly teach your patients to perform good tests or your PneumoCheck will continually find fault with maneuvers and you and your patient will quickly become frustrated.

To Obtain a Good FVC Result:

1. **Explain** the test and what you expect.

2. **Demonstrate** how to place the disposable mouthpiece in the mouth (teeth on the outside, forming a good seal with the lips).

3. **Demonstrate** how a maneuver is done by doing one yourself. Make sure your effort is a good one by inhaling all the way and then exhaling as completely and rapidly as possible either into the instrument or simply into the disposable mouthpiece.

4. **Coach** your patient throughout the test: "Now blast out hard and fast!! All you can!! More! More! Keep going a little more!"

5. **Learn** to recognize poor maneuvers by closely observing the patient:

   An acceptable maneuver requires:
   - adequate understanding
   - maximal inhalation
   - a rapid start of the effort
   - apparent maximal effort with continuous, steady exhalation
   - at least three seconds of exhalation (the ideal is six to ten seconds)

Unacceptable conditions include:

- slow or hesitating start
- air leaking around the mouthpiece
- coughing during the first second of the maneuver
- mouthpiece obstruction by tongue, lips, or teeth
- quitting too soon

6. When the maneuver has been completed, observe the quality message. If a message appears indicating an unacceptable maneuver (see p. 49), instruct the patient on how to correct the problem and repeat the test.

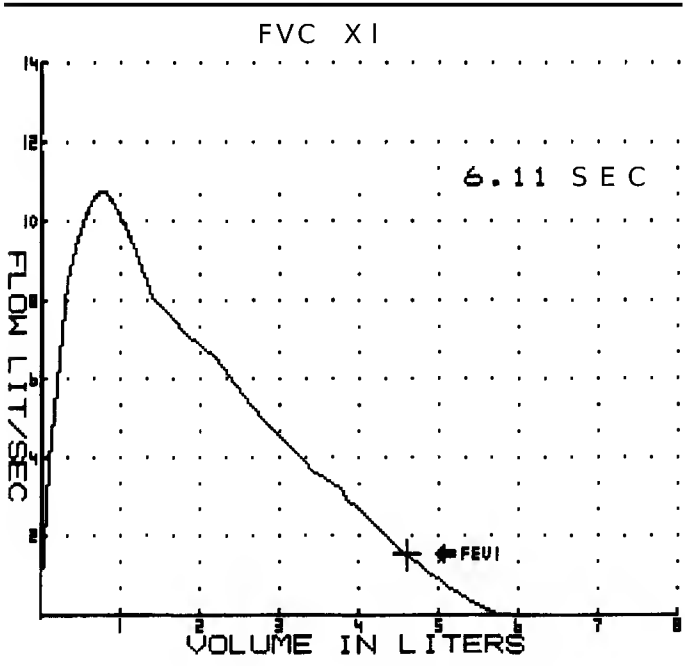
Example of Acceptable (GOOD FVC) Effort:

AGE: 23 **HEIGHT:7Zin** RACE: 2 SEX: M

	ACTUAL	NORM	%NORM	ABN
FVC	5.74	5.60	102	
FEV1	4.60	4.84	95	
FEV1/FVC%	80%	86%	93	
FEF25-75%	4.19	5.38	78	
PEF	10.81	10.02	108	

NORMS: Knudson 1983 (VS30P30)

Good FVC maneuver.



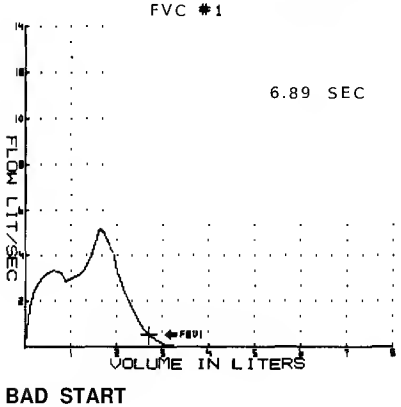
Examples of Unacceptable Efforts:

AGE: 37 HEIGHT: 66in RACE: 2 SEX: F

	ACTUAL	R	M	%NORM	ABN
FVC	3.25		3.62	90	
FEV1	2.71		3.04	89	
FEV1/FVC%	84%		84%	100	
MMEF25-75%	2.94		3.48	84	
PEF	5.13		6.55	78	

NORMS: Knudson 1983 (VS30P30)

Slow FVC start: **begin faster.**



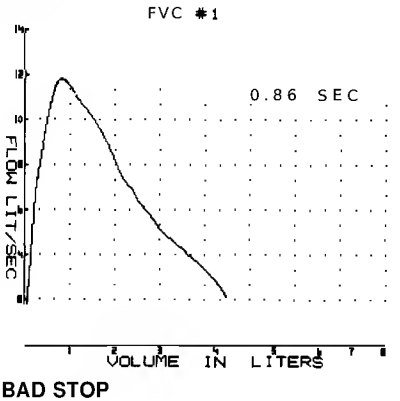
BAD START

AGE: 23 HEIGHT: 72 in RACE: 2 SEX: M

	ACTUAL	NORM	%NORM	ABN
FVC	4.51	5.83	77	*
FEV1	4.51	4.82	94	
FEV1/FVC%	100%	83%	120	
MMEF25-75%	6.69	4.97	134	
PEF	11.82	10.02	118	

NORMS: Crapo 198 1 (VS30P30)

Sudden termination of FVC.
FVC too short: blow out longer.



BAD STOP

AGE: 23 HEIGHT: 72in RACE: 2 SEX: M

	ACTUAL	NORM	%NORM	RBN
FVC	6.00	5.60	107	
FEV1	4.66	4.84	96	
FEV1/FVC%	[illegible]	86%	71	
MMEF25-75%	4.[illegible]	3.[illegible]	75	
PEF	9.76% 30	10.02	83	

NORMS: Knudson 1983 (VS30P30)

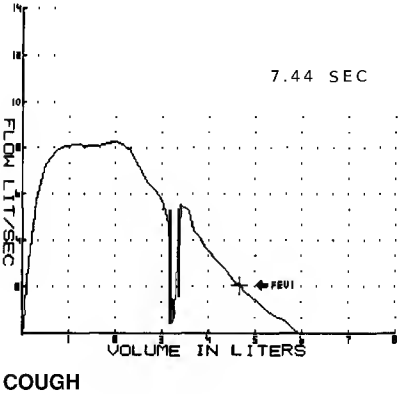
FVC interrupted: avoid coughing.

AGE: 23 HEIGHT: 72in RACE: 2 SEX: M

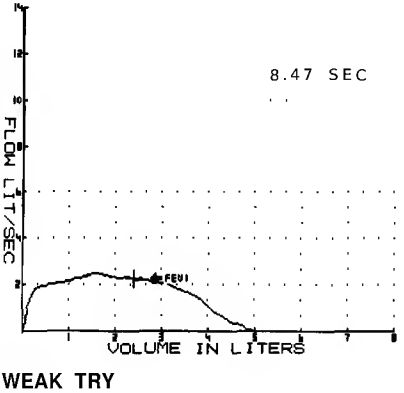
	ACTUAL	R	M	%NORM	ABN
FVC	4.93		5.60	88	
FEV1	2.43		4.84	50	
FEV1/FVC%	49%		86%	57	***
MMEF25-75%	2.12		5.38	39	***
PEF	2.48		10.02	25	***

NORMS: Knudson 1983 (VS30P30)

Weak FVC **effort**: blast harder.



COUGH



WEAK TRY

DOING AN FVC MANEUVER

1. Upon selection of FVC, the PneumoCheck first measures zero airflow through the pneumotach to assure maximum accuracy. During this time (no more than seven seconds) the word STEADY is displayed and it is important to hold the Pneumo-Check still so that an accurate reference can be made. If the PneumoCheck is moved during this time, the STEADY message will remain until it is held quite still for at least three seconds, or until an UNSTEADY message appears. Should an UNSTEADY message appear, depress the TEST button to start FVC again.

2. The PneumoCheck then displays the message DO FVC 1, and beeps.

3. The patient may sit or stand, but position should be noted,,. A sitting position is often preferred for stability.

4. Instruct the patient to inhale deeply, put the mouthpiece in his/her mouth and exhale as completely and with as much force as possible.

   After completely emptying the lungs, the patient removes the instrument from the mouth. The PneumoCheck will beep after about four seconds, indicating it has seen the end of the maneuver.

NOTE: Inhalation should not be done through the pneumotach. Back end of pneumotach should not be blocked.

In performing an FVC maneuver the patient's lips and teeth should be placed around the mouthpiece, with the lips forming a

seal. The mouth should be opened wide enough to avoid any obstruction by the teeth or tongue.

5. The PneumoCheck will then display BUSY while calculating test results. It will then provide a series of messages. The first message appears automatically, and gives an indication of the patient's effort. The message for an acceptable effort is GOOD FVC. For a complete list of the other quality control messages see p. 49.

6. Press and release the DATA button consecutively to see additional quality messages and each of the calculated parameters for the maneuver: FVC, FEW, RATIO (or FEV 1/ FVC%), MMEF (or FEF 25%-75%), and PEF. For a definition and discussion of these values, refer to Interpretation of Results (P. 17).

7. Press the TEST button to return to SELECT.

DOING MULTIPLE TESTS ON A PATIENT

According to the American Thoracic Society recommendations for testing,,, the patient should perform at least three acceptable FVC maneuvers, the best two of which must match one another within 5%. The best effort is then used to assess patient status.

No more than eight maneuvers should be obtained to avoid fatiguing the patient.

This is easily accomplished with your Welch Allyn PneumoCheck as it will automatically:

1. Assess acceptability.
2. Save the best test.
3. Determine repeatability ("matching").

Following is a description of the specifics:

When power is first turned on, the instrument's memory is empty as indicated by the CLEAR message.

The PneumoCheck automatically stores all test data for the best FVC and the best MVV as well as the most recent FVC and MVV maneuvers. To review BEST or LAST test:

Press TEST button to access SELECT.
Press DATA button once and release to access BEST FVC.
Press DATA button again and release to access LAST FVC.
Press DATA button and release a third time to return to SELECT.

After accessing BEST or LAST memory, wait three seconds for the quality control message. Then, push and release DATA to see calculated values for that test.

ASSESSING ACCEPTABILITY:

The PneumoCheck will determine whether the maneuver just performed should replace the maneuver that was previously stored as BEST test. In making this determination, the PneumoCheck first looks at the quality control messages for the new maneuver. A "good" maneuver is one that has no identifiable faults, such as a cough in the middle of the maneuver or a hesitating start (see p. 8).

SELECTING BEST TEST:

One Acceptable, One Not

If the new maneuver is acceptable and the previously stored BEST maneuver was not, then the previously stored BEST maneuver is discarded and the new maneuver is stored in its place.

Likewise, if the new maneuver is not acceptable while the previously stored BEST maneuver was acceptable, then the previously stored BEST maneuver is retained.

Both Acceptable, Both Unacceptable

If the stored BEST maneuver and the new maneuver are both acceptable or both unacceptable, the PneumoCheck next determines which is BEST based on the following criteria:

Criterion For Best FVC Maneuver:
The larger sum of the FVC and FEVl

Criterion For Best MVV Maneuver:
The higher value as expressed in liters/minute.

DETERMINING REPEATABILITY:

In addition to selection of the best test, it is important to know that the tests were reproducible, that is, to know that they matched. To do this the currently stored best test is compared to the most recent test and a message appears after the quality message.

Match Criteria

FVC

The previously stored best maneuver and the new maneuver are compared:

- MATCH will be displayed if both FVC values are within 5% of each other and both FEVI values are within 5% of each other.

If both FVC values and both FEVI values are not within 5% of each other:

- NO MATCH will be displayed if the new maneuver is 5% less than the previously stored BEST.
- NEW BEST will be displayed if the new maneuver is 5% greater than the previously stored BEST.

MVV

- MATCH will be displayed if the MVV values of the two tests being compared are within 15% of each other.
- NO MATCH will be displayed if the MVV values compared are not within 15% of each other.

Remember that results displayed at the completion of the maneuver are for the maneuver just completed. See p.14 for instructions on accessing BEST and LAST tests.

NOTE: Turn the ON/OFF switch to OFF and back to ON before beginning a test on a new patient, so that the previous patient data memory is cleared.

INTERPRETATION OF RESULTS

The PneumoCheck Printer/Charger will place a star beside values which are abnormal, [11]. If the FEVI/FVC ratio is abnormally low, an obstructive disorder is indicated. Use the FEVI to grade the severity of the obstruction:

- An FEVI above 80% of predicted indicates a **Borderline Obstruction.**
- An FEV1 between 60% and 80% of predicted indicates a **Mild Obstruction.**
- An FEVI between 40% and 60% of predicted indicates a **Moderate Obstruction.**
- An FEVI below 40% of predicted indicates a **Severe Obstruction.**
- If the FEVI is below 80% of predicted and the FVC is also below 80% of predicted, the possibility of a superimposed Restriction in addition to the Obstruction exists.

If **the FEVI/FVC ratio is normal, but the FVC is abnormal, a restrictive disorder is indicated, and the FVC is used to grade the severity of the restriction:**

- An FVC between 60% of predicted and the lower limit of normal indicates a **Mild Restriction.**
- An FVC between 50% and 60% of predicted indicates a **Moderate Restriction.**
- An FVC below 50% of predicted indicates a **Severe Restriction.**

Any patient who has a normal FVC, FEVI/FVC, and FEF 2575% is considered to be within normal limits, and clinically significant obstructive lung disease can be ruled out. An exception to this is the asymptomatic asthmatic who is in remission.

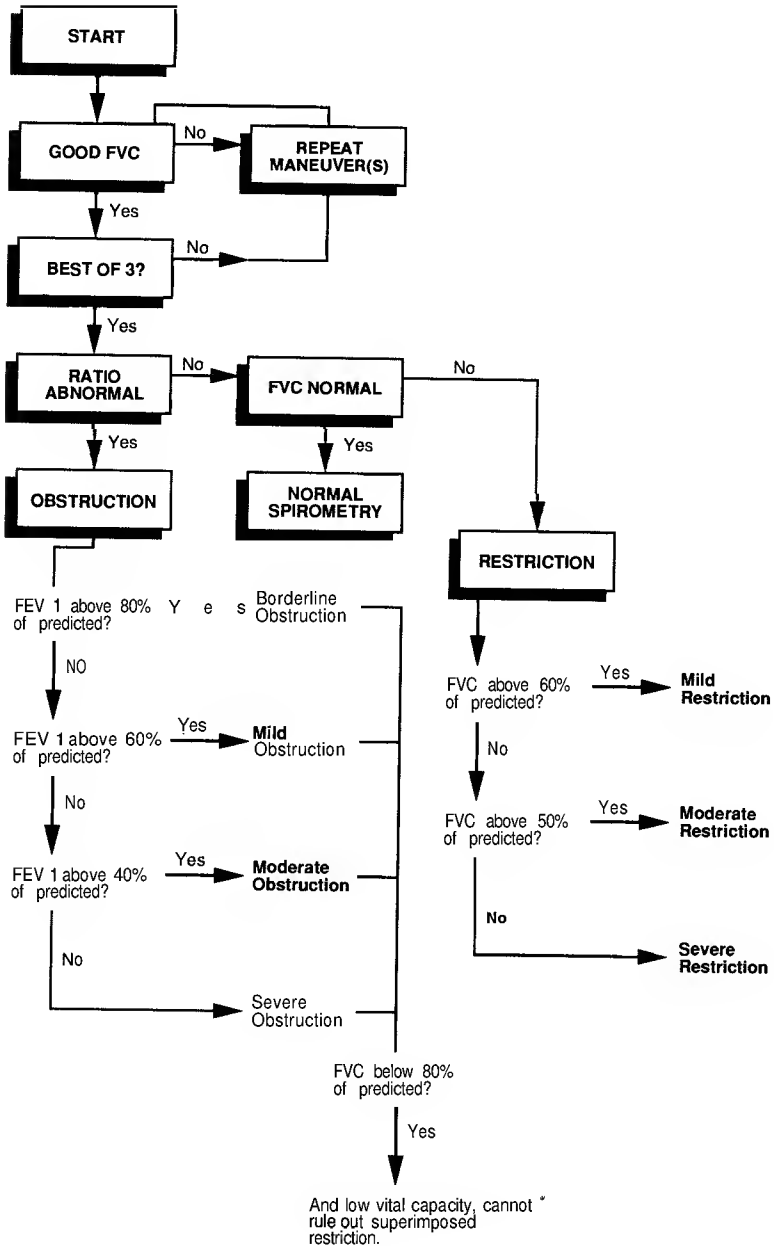
SPECIAL NOTES:

- A normal spirometry test does not preclude the existence of lung cancer or the very early stages of many of the restrictive lung disorders.

- If both the FEVI and FEVI/FVC ratio are normal, some pulmonary specialists will examine the FEF 2575% (MMEF). If it is low, the patient may have a 'slight obstruction.' There is some controversy regarding this variable and its clinical significance in indicating small airways dysfunction.'

- It is risky to attempt the interpretation of results when acceptable and reproducible maneuvers were not obtained. To do so may yield false positive results.

INTERPRETATION OF FVC RESULTS FLOW CHART, [11]



THE MVV TEST

DESCRIPTION

The MVV or Maximal Voluntary Ventilation is another type of spirometry test. When doing an MVV, the patient is required to breathe in and out as deeply and as rapidly as possible for a period of 12 to 15 seconds.

Specific indications for doing the test are:

1. Social Security evaluation for total disability from COPD.
2. Determination of coal miners' total disability due to pneumoconiosis.
3. Biannual pulmonary surveillance of employees exposed to cotton dust.
4. Preoperative evaluation of overall breathing ability.
5. Evaluation of dyspnea unexplained by the FVC maneuver,,.

MEASUREMENT PARAMETERS

The parameters that are measured during an MVV maneuver are:

- **The MVV:** The total amount of air (in liters per minute) moved by the lungs during the test.
- MVV **Rate:** The breathing rate (in breaths per minute).
- MVV **Time:** The elapsed time (in seconds) of the usable portion of the maneuver.

NOTE: During MVV maneuvers in the normal operating mode, the instrument assumes that air at body temperature and pressure, fully saturated with water (BTPS) will be used, and a BTPS factor is applied.

OBTAINING GOOD MVV RESULTS

MVV results are also extremely effort-dependent.

Obtaining a Good MVV Result:

1. Explain the test and what you expect.

2. Demonstrate how to put the disposable mouthpiece in the mouth (teeth on the outside, forming a good seal with the lips).

3. Demonstrate how a maneuver is done by breathing in and out quickly and deeply for a few seconds.

4. Coach your patient throughout the test.

5. Learn to recognize most poor maneuvers by observing the patient:

   An acceptable maneuver requires:
   - at least six seconds of test time
   - a rapid pace

   Unacceptable conditions include:
   - air leaking around the mouthpiece
   - mouthpiece obstruction by tongue, lips, or teeth
   - quitting too soon

DOING AN MVV MANEUVER

1. Upon selection of MVV the PneumoCheck first measures zero airflow through the pneumotach to assure maximum accuracy. During this time (no more than seven seconds) the word STEADY is displayed and it is important to hold the PneumoCheck still so that an accurate reference can be made. If the PneumoCheck is moved during this time, the STEADY message will remain until the PneumoCheck is held quite still for at least three seconds, or until an UNSTEADY message appears. Should an UNSTEADY message appear, depress the TEST button to start MVV again.

2. The PneumoCheck then displays the message DO MVV 1, and beeps.

3. The patient performs an MVV maneuver by inhaling deeply, placing the instrument in the mouth, and then panting forcefully through the pneumotach, beginning with an exhalation. The patient should continue until the PneumoCheck beeps (15 seconds after the start of the maneuver). Patient should not block the back end of the pneumotach.

4. Upon completion of the maneuver, the word BUSY will be displayed while the PneumoCheck calculates the results. The quality control message will then be displayed.

5. Press and release the DATA button consecutively to see additional quality messages and MVV test parameters. (See pp. 20 and 49 for more detail.)

6. Press the TEST button to return to SELECT.

DOING MULTIPLE TESTS ON A PATIENT
See page **14.**

ASSESSING ACCEPTABILITY
See page **15.**

SELECTING BEST TEST
See page **15.**

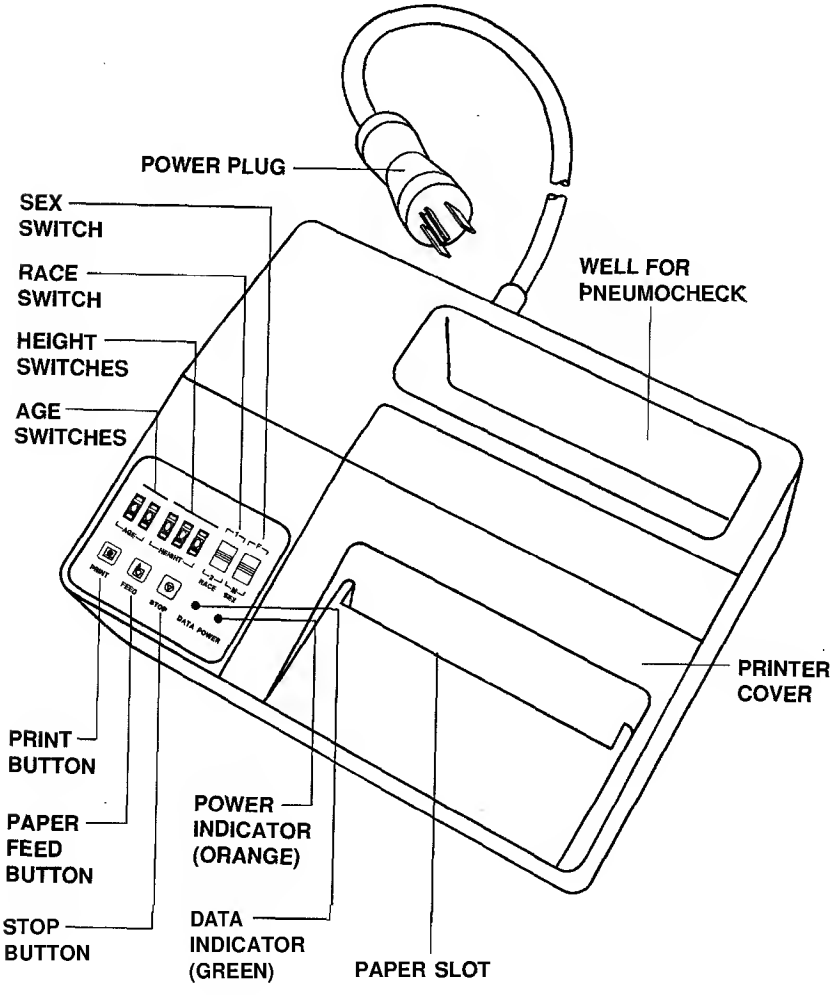
DETERMINING REPEATABILITY
See page **15.**

MATCH CRITERIA
See page 16.

INTERPRETATION OF RESULTS

MVV results have been found to correlate with the degree of dyspnea and the level of disability. An abnormal result may be caused by obstructive or restrictive lung diseases, respiratory muscle weakness, poor physical conditioning or neurological diseases. However, it should be noted that abnormal results could be produced by poor patient effort during the test.

PARTS OF THE PNEUMOCHECK PRINTER/CHARGER (#76100 OR #76105)



SETTING UP

1. Plug the power cord into the black receptacle in the rear of the Printer/Charger. Then connect the power cord to a receptacle of appropriate voltage, frequency and plug type. The orange power indicator on the front panel will become illuminated, and a two-tone beep will occur.

2. Leave the power switch of the PneumoCheck spirometer in the ON position after a test to print a report. Turning the Pneumo-Check OFF will clear the memory of all data.

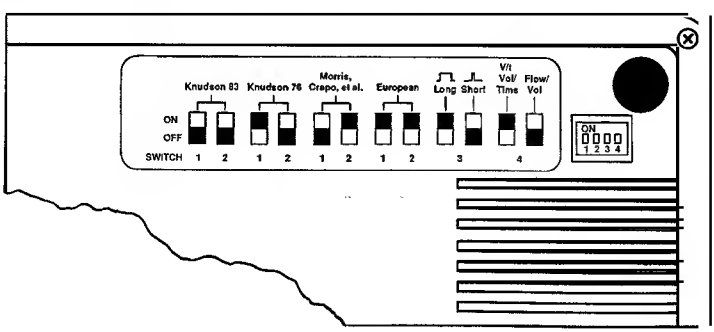
3. ONLY the results from the BEST test will be printed.

4. If individual prints of each test are desired (e.g. for inhalation challenges, evaluations for Social Security Disability, etc.):

   . Print the very first maneuver.
   . Turn the PneumoCheck OFF and then back ON to clear memory before performing the next maneuver.
   . Repeat above two steps for each maneuver.

SETTING REPORT FORMAT OPTIONS

On the underside of the Printer/Charger is a set of four option switches. With these switches you can specify report format as follows:



PREDICTED NORMALS **(Switches 1 and 2)**

Four sets of predicted normal values are provided for comparing patient results. The standard factory setting is Knudson, 1983. Use option switches one and two to change this setting. For more information on predicteds see Appendix C (p. 51).

SHORT FORM OR LONG FORM (Switch 3)

Choose between the Short Form,and the Long Form report by using the third switch. The Long Form includes a respiratory history questionnaire which allows you to record the patient's respiratory history:

SHORT FORM

NAME : _____

DRTE : _____ ID: _____

LONG FORM

NAME : _____

DATE : I D : _____

AGE 36 HEIGHT: 66in RACE: 2 SEX: F

Reason for test _____

Cough? _____ Sputum? _____

Smoker? Pack-years? _

Quit? _____ Whm? _____

Dgspnea? _____ When? _____

Chest Pain? _____

Heart Disease? _____

Wheeze/Asthma? _____

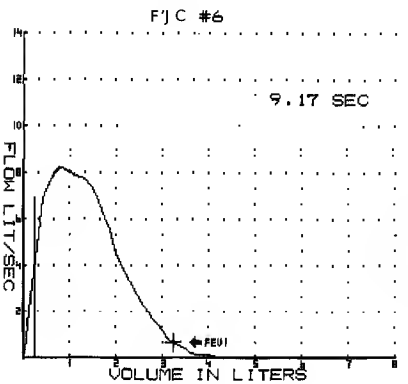
CUtlS Surgery _____

Abn. . Chest X-Ray? _____

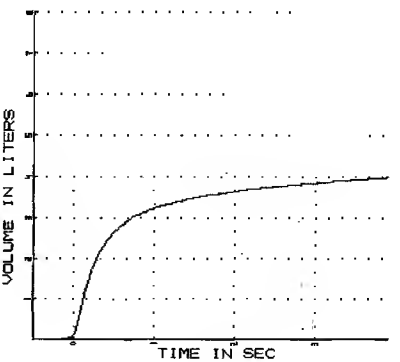
FLOW/VOLUME PLOT OR VOLUME/TIME PLOT (Switch 4)

Choose a Flow/Volume plot or a Volume/Time plot for FVC maneuvers using the fourth switch. See examples below:

FLOW/VOLUME



VOLUME/TIME



BEST FVC

This value cites, per ATS recommendations,,, the largest single FVC value from all acceptable maneuvers.

BEST FEV1

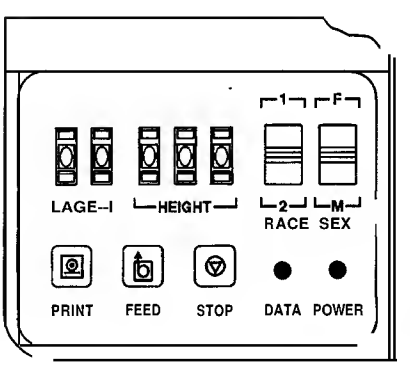
This value cites, per ATS recommendations,,, the largest single FEVI value from all acceptable maneuvers.

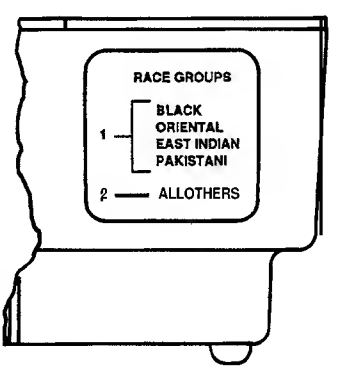
ENTERING PATIENT DATA

1. Set the AGE and HEIGHT values by pressing the switches above or below each number. Height can be set in either inches or centimeters. (If the height entered is greater than 84, centimeters will be assumed.) Height should be measured accurately in stocking feet since it has the largest effect on predicted value.

2. To set the RACE switch, use the UP position for RACE 1: Blacks, Orientals, East Indians, and Pakistanis, and the DOWN position for RACE 2: all other races including Caucasians and Hispanics.

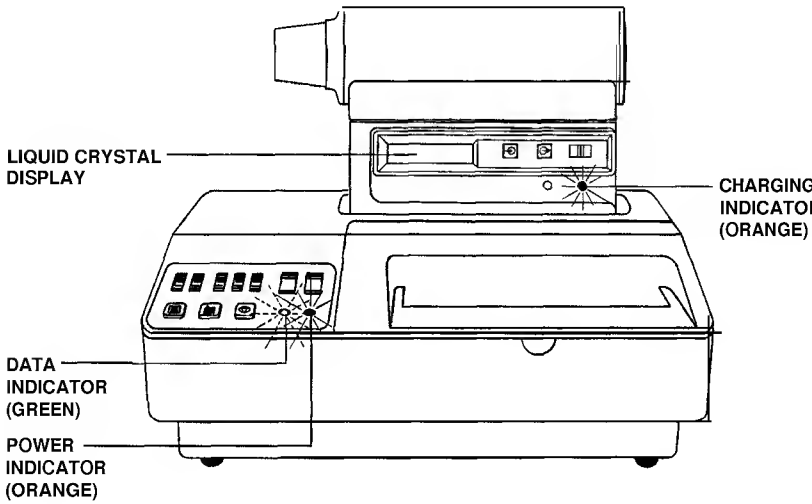
3. To set the SEX switch, use the UP position (F) for female and down (M) for male.





PRINTING

1. Place the PneumoCheck in the Printer/Charger well with the display facing you. When the instrument is properly seated, the orange charging indicator on the PneumoCheck will become illuminated.



2. The green DATA indicator on the Printer/Charger will flash during data transfer and the PneumoCheck Liquid Crystal Display will display SEND FVC and/or SEND MVV or SEND CAL. When data transfer is complete, the green DATA indicator will stop flashing and a triple tone beep will occur.

   NOTE: Instrument may be removed after data transfer; data will remain in printer memory until new data is entered or power is disconnected.

3. Press the PRINT button momentarily to begin printing. A full FVC report takes approximately 20 seconds to print.

4. Tear the report off by pulling the paper towards you.

5. For a duplicate report, press the PRINT button again.

PAPER FEED

To feed extra paper, depress the FEED button. Paper will continue to feed as long as the button is depressed.

PAPER JAMS

If the paper has wrapped around the gray rubber pinch roller several times, feed the paper backwards:

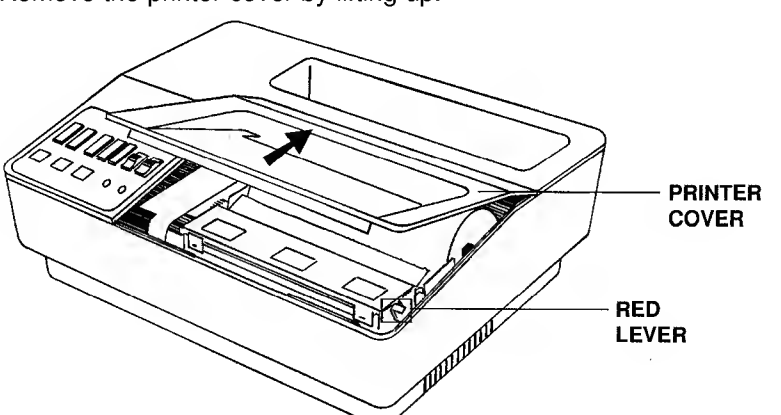
1. Depress the STOP button and the FEED button simultaneously, then release the STOP button.

2. The printer will feed backwards continuously until you release the FEED button.

For paper jams that do not involve paper wrapping around the pinch roller, cut the paper from the roll, and pull the paper out from the top of the printer. *Do* not pull *the paper backwards through printer.*

PAPER REPLACEMENT

1. Remove the printer cover by lifting up.



2. Feed any remaining paper through the printer. *Do not pull paper backwards through printer.* Remove and discard old paper roll, saving black plastic spindle.

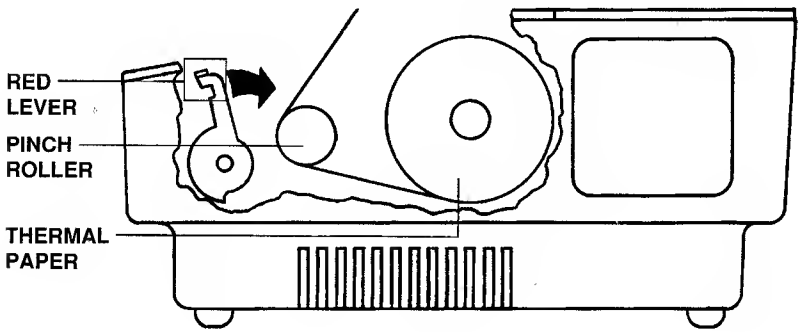
3. Cut end of new roll squarely, and insert black plastic spindle.

4. Pull the red lever to its forward position.

5. Place the new roll of paper in the printer well, insuring that spindle is located behind retaining blocks, and that the paper feeds forward from the bottom of the roll.

6. Insert edge of paper under the gray rubber pinch roller until paper exits top of printer.

7. Push the red lever as far back as possible.



8. Press the FEED button to feed through several inches of paper.

9. Replace the printer cover taking care to feed paper through opening.

   NOTE: This is thermally activated paper. If paper is inserted backwards, no printing will appear on paper.

STOPPING THE PRINTER

The STOP button on the Printer/Charger serves two functions:

I Press STOP to abort current operation (report printing or data transfer).

2. Press STOP to clear Printer/Charger of error condition.

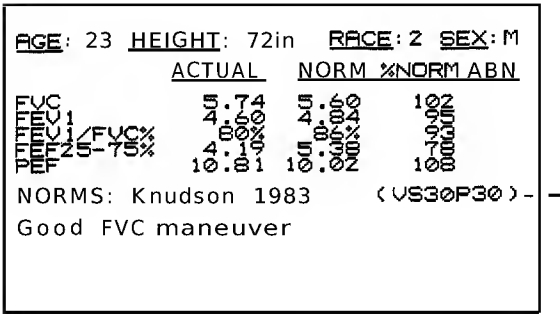
   NOTE: If a test is stored in the Printer/Charger memory, it will remain there and can be printed after the STOP button has been pressed.

ERROR CONDITIONS

If the Printer/Charger should detect an error, it will generate an audible alarm and flash the DATA light in groups of 1, 2, or 3 flashes which correspond to the error that was detected:

- 1 FLASH - There is no paper in the printer, or the printer lever is in the wrong (forward) position.
- 2 FLASHES - A hardware malfunction has occurred. Press the STOP button to clear the problem. If the error recurs, the Printer/Charger may need servicing.
- 3 FLASHES - Data received from the PneumoCheck is invalid. Press STOP, and retransmit data by removing the Pneumo-Check from the Printer/Charger well temporarily. If the error recurs, turn the PneumoCheck OFF, clear the Printer/Charger by pressing STOP again, and retest the patient. If the problem persists, your PneumoCheck, Printer/Charger, or both, may require servicing.

NOTE: The version of software in your PneumoCheck Printer/ Charger is printed on each printout just beneath the chart of values.


AGE: 23 HEIGHT: 72in RACE: 2 SEX: M
ACTUAL NORM %NORM ABN
FVC 5.74 5.60 102
FEV1 4.60 4.84 95
FEV1/FVC% 80% 86% 93
FEF25-75% 4.19 5.38 78
PEF 10.81 10.02 108
NORMS: Knudson 1983 (VS30P30)
Good FVC maneuver
SOFTWARE VERSION

The ATS Recommendation

The American Thoracic Society recommendation for recalibration is as follows:

> "The spirometer's ability to accurately measure volume should be checked at least daily with a calibrated syringe with a volume of at least 3.0 liters. During industrial surveys or other field studies in which a large number of subject maneuvers are done, the equipment should be calibrated prior to testing daily if in regular use and then every 4 hours during use. Although there is minimal day-to-day variation in volume calibration, daily calibration checking is highly recommended so that the onset of a problem can be determined within one day, eliminating needless reporting of false values for several weeks or months and also to help define day-to-day laboratory variability. For survey testing where a large number of maneuvers are done, the 4-hour period of calibration checking is recommended to prevent invalidation of data from a large number of maneuvers,,."

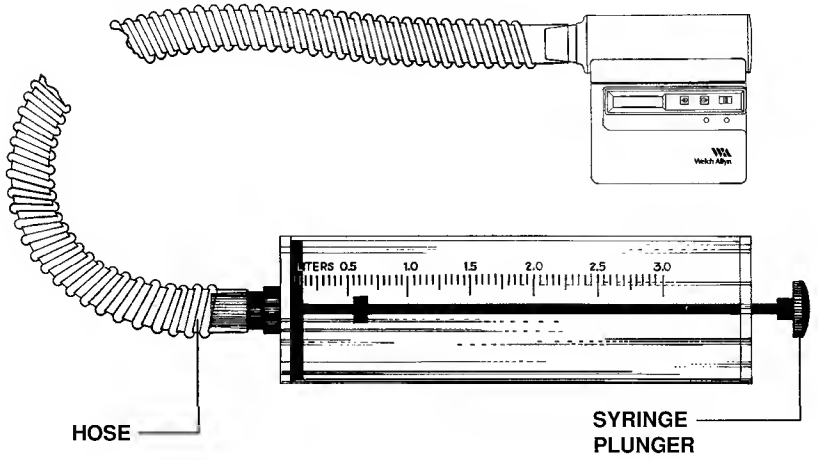
Check calibration and recalibrate if necessary any time there has been a change in elevation of 200 feet or more.

Check the calibration and recalibrate if necessary whenever the pneumotach assembly has been replaced for any reason, i.e. cleaning, sterilization, changing the battery.

Examine the screen of your PneumoCheck daily. Blockage of the screen indicates the need for cleaning the screen (see p. 41) followed by a calibration check.

CALIBRATION CHECK

Attach a calibrated 3.0 liter syringe (stored at the same temperature as your PneumoCheck) with appropriate hose (see Accessories on p. 43).



2. Make sure that nothing is blocking the back end of the pneumotach.

3. Flush the syringe back and forth through the PneumoCheck several times to equilibrate the temperature.

4. Pull the syringe plunger back as far as it will go.

5. Access the TEST.MODE on your PneumoCheck:

   (a) Turn vour PneumoCheck OFF.
   (b) Whiledepressing the TEST button turn the instrument ON.
   (c) The message TEST.MODE will appear briefly and a beep will sound.
   (d) The message VER X.X will be displayed. This indicates the software version used in your PneumoCheck.
   (e) Then the CLEAR and SELECT messages will be displayed.

6. Depress TEST button to select FVC.

7. When the PneumoCheck indicates DO FVC 1, push the plunger forward as far as it will go using an even, consistent motion. This forward stroke should take l-2 seconds.

8. The PneumoCheck will then display BUSY while calculating test results, and will then display TEST.MODE.

9. To review the result press the DATA button. Results between 2.91 liters and 3.09 liters indicate an accurate instrument (+3% of 3.0 liters as specified by ATS).

10. Print the TEST.MODE FVC result if documentation of the calibration check is desired.

11. Return to regular operating mode by turning the power OFF, then ON again.

NOTE: There is no quality check done on calibration check maneuvers nor is best test selected. Every test is stored, replacing the previously stored test.

RECALIBRATION

Recalibrate your PneumoCheck anytime a calibration check shows it to be inaccurate (see ATS recommendation on p. 31).

1. With the PneumoCheck OFF, connect the 3.0 liter syringe (stored at the same temperature as your PneumoCheck) to the pneumotach, portion of the PneumoCheck.

2. Make sure that nothing is blocking the back end of the pneumotach.

3. Flush the syringe back and forth several times through the PneumoCheck to equilibrate the temperature.

4. Turn the PneumoCheck ON. When SELECT message is displayed, select the calibration (CAL) mode (see p. 4).

5. Pull back the plunger of the syringe when a double beep occurs and the PULL.BACK message appears.

6. The PneumoCheck will display the STEADY message, then RETRIM for approximately 45 seconds while measuring zero flow through the pneumotach to assure maximum accuracy.

7. When a single beep and the message DO CAL 1 appears, wait one second, then push the plunger all the way forward using an even, consistent motion. This forward stroke should take less than one second.

8. The PneumoCheck will display the message BUSY briefly and then PULL.BACK again. Three maneuvers must be completed in order to recalibrate the unit: repeat steps 5 and 7 twice more. Notice that with each subsequent calibration maneuver, the messages DO CAL 2 and DO CAL 3 will appear instead of DO CAL 1.

9. Once three maneuvers have been completed, the Pneumo-Check will calculate the average volume of the three maneuvers. Each maneuver is then compared to this calculated average, and if all three are within 0.5% of the calculated average, the calibration value is automatically updated and displayed as CF=xxxx, followed by, the message GOOD CAL .

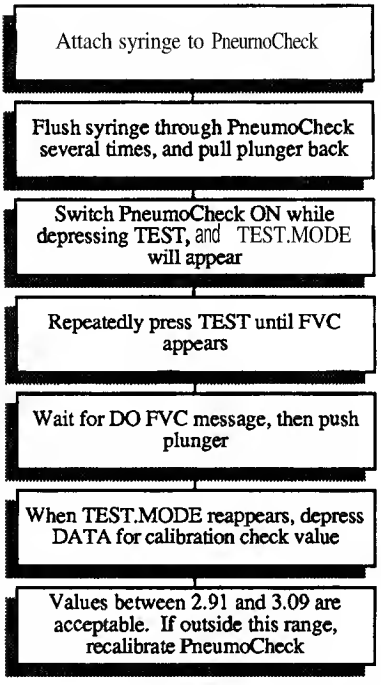
10. If any of the calibration maneuvers were not within 0.5% of the dalculated average, a triple beep will occur and the message RETRY.CAL will be displayed, and the existing calibration factor will not be updated. Attempt recalibration again.

11. Do a calibration check and produce a printout if desired (see p. 32).

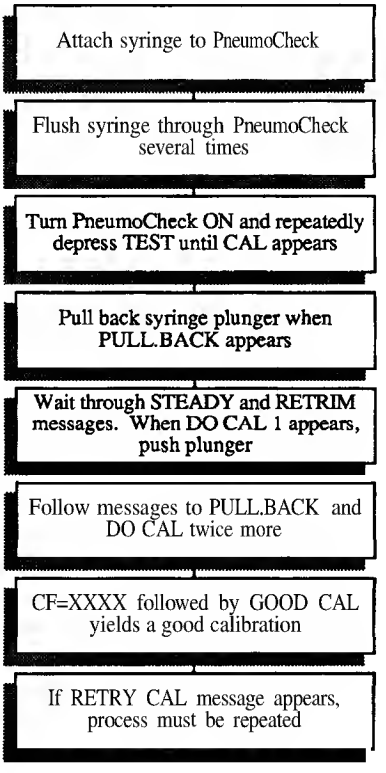
NOTE: When checking calibration in TEST.MODE, or when recalibrating, the instrument assumes room air will be used and an Air Temperature and Pressure Dry (ATPD) factor is applied. ATPD will appear at the top of the calibration check printout.

QUICK CALIBRATION CHECK AND RECALIBRATION REFERENCE CHARTS

Doing a Calibration Check


Attach syringe to PneumoCheck
Flush syringe through PneumoCheck several times, and pull plunger back
Switch PneumoCheck ON while depressing TEST, and TEST.MODE will appear
Repeatedly press TEST until FVC appears
Wait for DO FVC message, then push plunger
When TEST.MODE reappears, depress DATA for calibration check value
Values between 2.91 and 3.09 are acceptable. If outside this range, recalibrate PneumoCheck

Doing a Recalibration


Attach syringe to PneumoCheck
Flush syringe through PneumoCheck several times
Turn PneumoCheck ON and repeatedly depress TEST until CAL appears
Pull back syringe plunger when PULL.BACK appears
Wait through STEADY and RETRIM messages. When DO CAL 1 appears, push plunger
Follow messages to PULL.BACK and DO CAL twice more
CF=XXXX followed by GOOD CAL yields a good calibration
If RETRY CAL message appears, process must be repeated

BATTERY MAINTENANCE

The PneumoCheck will remain charged and ready for use if returned to Printer/Charger when not in use.

BATTERY RECHARGING

The nickel cadmium batteries in the PneumoCheck will provide approximately 8 hours of continuous operation on a full charge. When the batteries are low, the message LOW BATT will be displayed, and the PneumoCheck will not allow any tests until the batteries have been recharged.

NOTE: After LOW BATT appears, printing of the most recent test in the PneumoCheck memory is still possible.

A fully drained battery may be fully recharged in about 15 hours by either of these methods:

PRINTER/CHARGER

1. Connect the power plug of the Printer/Charger to a receptacle of appropriate voltage, frequency and plug type. The orange power indicator will become illuminated.

2. Place the PneumoCheck into the charging well with the display facing you. When properly seated, the orange charging indicator on the PneumoCheck will become illuminated.

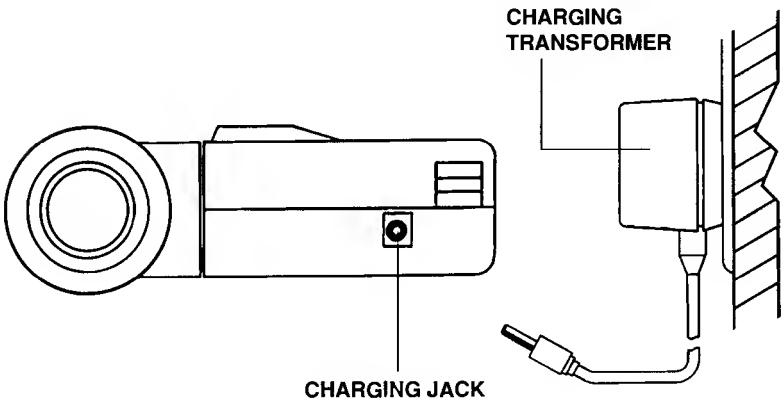
CHARGING TRANSFORMER

⚠**CAUTION:** USE ONLY A WELCH ALLYN CHARGING TRANSFORMER (SEE P. 43) TO AVOID HAZARDS OF FIRE, SHOCK, OR DAMAGE TO THE INSTRUMENT.

To recharge:

1. Plug the charging transformer into a receptacle of appropriate voltage, frequency and plug configuration.

2. Place the PneumoCheck on its back and plug the output cord of the transformer into the charging jack of the PneumoCheck.



SPECIAL NOTES

1. Slight heating of the PneumoCheck during charging is normal.

2. Batteries will not leak.

3. If left without charge, batteries will discharge gradually over a period of about 30 days when stored at room temperature (70" F). Storage at higher temperatures will accelerate the discharge rate.

4. The batteries will last longer if used on a regular basis.

5. The PneumoCheck may be charged indefinitely without damage to the batteries.

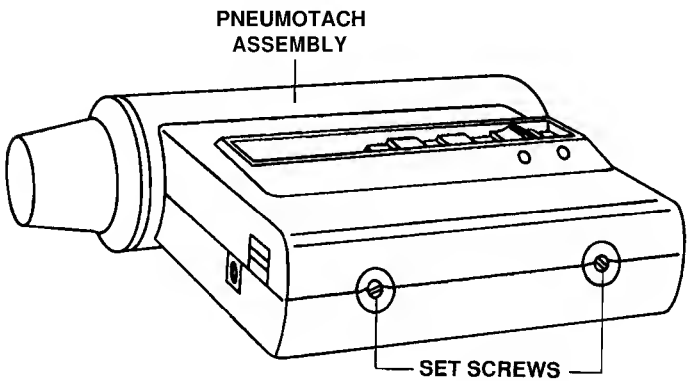
BATTERY REPLACEMENT

The PneumoCheck batteries are intended for many charge/recharge cycles and are warranted for two years (expiration date is imprinted on each battery). For maximum battery life, always replace both batteries at the same time.

To replace:

1. Turn the PneumoCheck OFF.

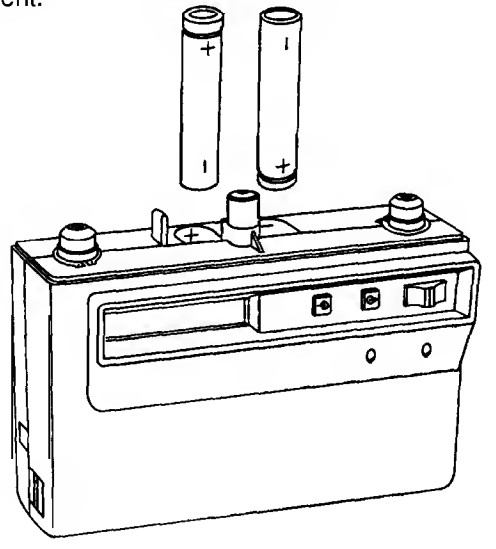
2. Using a coin, loosen the two set screws on the bottom of the PneumoCheck (these screws will loosen, but cannot be removed).



3. Remove the pneumotach assembly from the top of the PneumoCheck.

4. To remove the batteries, turn the PneumoCheck upside down and tap lightly.

5. Insert new batteries according to diagram inside battery compartment.



6. Replace the pneumotach assembly and tighten the two screws on the bottom until the pneumotach is securely in place.

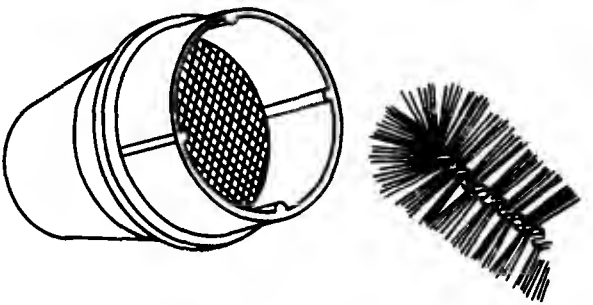
7. Recalibrate the PneumoCheck (see p. 34).

⚠**CAUTION:** REPLACE WITH WELCH ALLYN NO.72500 BATTERIES ONLY. USE OF BATTERIES OF OTHER MANUFACTURE MAY CAUSE RISK OF FIRE OR DAMAGE TO THE UNIT.

PNEUMOTACH

The screen in the pneumotach mouthpiece should be visually inspected before each use.

If sputum or other foreign matter becomes lodged in the screen, it can cause erroneous readings. To clean the screen, remove the mouthpiece and scrub it with a small brush. Then check calibration (see p. 31).



The pneumotach assembly should be removed (see p. 39), cleaned and sterilized prior to any maneuvers involving inhalation, such as MVV.

Routine maintenance of the pneumotach assembly should include cleaning and sterilization after every 50 maneuvers.

The pneumotach will withstand the effects of cleaning and/or sterilization by any of the following methods:

Steam Autoclave (270" F, 27 PSI, 6 min cycle)
Ethylene Oxide
Cidex™
Cidex 7™
70% Isopropyl Alcohol
Boiling Water (30 min)

If using steam autoclave, instrument should be wrapped. Do not assume that pneumotach is completely dry after drying cycle. See drying instructions on p. 42.

If Cidex, Cidex 7 or Isopropyl Alcohol is used, rinse the pneumotach assembly thoroughly afterwards by immersing it in water and agitating vigorously to remove all traces of the solution. Then shake the pneumotach to remove excess water.

Regardless of the sterilization method chosen, insure that the pneumotach is completely dry before using. A wet or damp pneumotach will not be linear, and will cause inaccurate measurements:

For air drying, allow 4 days.

Using a hair dryer on high setting, allow **10** minutes.

Note that spare pneumotach assemblies are available (see p. 43) and can be used interchangeably.

THE PNEUMOCHECK SHOULD BE RECALIBRATED ANY TIME THE PNEUMOTACH HAS BEEN REMOVED/REPLACED.

BODY OF PNEUMOCHECK

The body of the PneumoCheck may be cleaned by wiping with a dry cloth or a cloth that has been lightly dampened with 70% Isopropyl alcohol. Care should be taken to prevent seepage of liquid into the instrument.

DO NOT IMMERSE OR STERILIZE THE BODY OF THE PNEUMOCHECK.

PRINTER/CHARGER

The PneumoCheck Printer/Charger should not be sterilized. It may be cleaned by wiping with a dry cloth.

CHARGING TRANSFORMERS

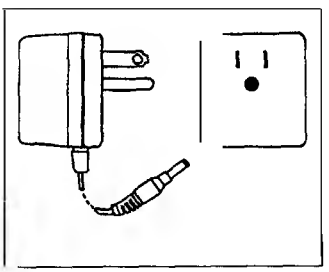
Charging transformers must not be sterilized, but may be cleaned by wiping with a dry cloth.

ACCESSORIES

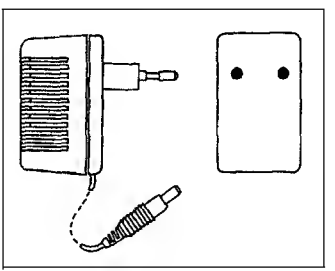
61050	Pneumotach Assembly.
610064-501	Pneumotach Mouthpiece
56100	Thermal Paper - 5 Rolls/Box, 12 Boxes/Case.
56120	Disposable Mouthpieces, Pediatric - 100/Bag, 5 Bags/Case.
56121	Disposable Mouthpieces, Adult - 100/Bag, 5 Bags/Case.
56130	Disposable Nose Clips - 100/Box, 4 Boxes/Case.
61010	Hose for 3.0 Liter Syringe.
61020	3.0 Liter Calibration Syringe Only.
61030	3.0 Liter Calibration Syringe and Hose.
72500	Two 3.6 V Rechargeable Batteries (7.2 V), Replacement.

Charging **Transformers**

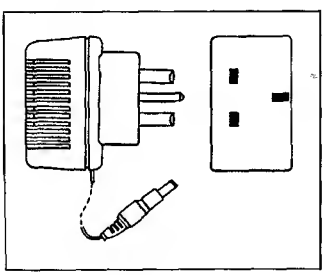
71040	UL/CSA 120 V nominal line voltage - (A)
71032	IEC 220-250 V nominal line voltage- (B)
71034	IEC 220-250 V nominal line voltage- (C)



(A)



(B)



(C)

76100	Printer/Charger Only.
76105	Same as 76100, but Export. Specify Country and Voltage.

WARRANTY

Welch Allyn warrants the PneumoCheck and Printer/Charger, when new, to be free of defects in material and workmanship and to perform in accordance with manufacturer's specifications for a period of two years from the date of purchase from Welch Allyn or its authorized PneumoCheck distributors or agents. Welch Allyn will either repair or replace any components found to be defective or at variance from manufacturer's specifications within this time at no cost to the customer. It shall be the purchaser's responsibility to return the instrument directly to Welch Allyn or to an authorized PneumoCheck distributor, agent or service representative. This warranty does not include breakage or failure due to tampering, misuse, neglect, accidents, modification or shipping. This warranty is also void if the instrument is not used in accordance with manufacturer's recommendations or if repaired by other than Welch Allyn or an authorized agent. Purchase date determines warranty requirements. No other express warranty is given.

Kindly submit instrument registration card for warranty validation.

REPAIR

Repairs must be done by authorized Welch Allyn personnel. Failure to do so will invalidate the warranty. Return to:

TECHNICAL SERVICE DEPARTMENT
WELCH ALLYN, INC.
4341 STATE STREET ROAD
SKANEATELES FALLS, NY 13153-0220
U.S.A.
(315) 6854445

Outside of the United States, return your PneumoCheck to your local authorized Welch Allyn distributor.

APPENDIX A
PNEUMOCHECK MESSAGES

PNEUMOCHECK STATUS MESSAGES

The following is a tabulation of the various messages that may be displayed on the PneumoCheck's Liquid Crystal Display:

BEST FVC The PneumoCheck has accessed the best FVC test from memory.

BEST MVV The PneumoCheck has accessed the best MVV test from memory.

BUSY The PneumoCheck is calculating the results of a test.

CAL The calibration maneuver has been selected and will begin in 3 seconds. Depress TEST button to select a different test.

CF=xxxx Shows the Calibration Factor after a successful calibration was completed. This value is now the new calibration value, replacing the old one that was previously stored in memory.

CLEAR The power has been recycled and the memory has been cleared.

DO CAL n The operator should perform the n^{th} calibration maneuver.

DO FVC n The patient should perform the n^{th} FVC maneuver.

DO MVV n The patient should perform the n^{th} MVV maneuver.

FLOW LIM Flow during a maneuver has exceeded the flow sensor's capacity of 14 liters/second.

FVC The FVC test has been selected and will begin in 3 seconds. Depress TEST button to select a different test.

LAST FVC The PneumoCheck has accessed the most recent FVC test from memory.

LAST MVV The PneumoCheck has accessed the most recent MVV test from memory.

LOW BATT The battery is too low to continue testing and requires recharging.

MVV The MVV test has been selected and will begin in 3 seconds. Depress TEST button to select a different test.

NEW BEST (FVC) This test has an FVC and/or FEVI which is more than 5% larger than the one currently stored as BEST test. It will replace the stored BEST test. See Doing Multiple Tests.on a Patient (p. 14).

NEW BEST (MVV) This test has a greater MVV than the one currently stored as BEST test. It will replace the stored BEST test. See doing Multiple Tests on a Patient (p. 14).

NO DATA A The maneuver was interrupted by the press of a key or a low battery.

NO DATA B The FVC or MVV maneuver did not start within 20 seconds after the beep.

NO DATA C The FVC terminated normally, but on analysis, no exhalation was found.

NO DATA D-G The maneuver appeared too fragmented, did not have enough breaths to analyze, or the breaths were too inconsistent or uneven. The maneuver analysis routine failed; the PneumoCheck was unable to analyze the data.

RETRIM The PneumoCheck is establishing a baseline for future data for calibration. In the RETRIM mode, the PneumoCheck uses a more accurate (and lengthy) approach than in the STEADY mode. The RETRIM message will be displayed for about 45 seconds.

SEND FVC The PneumoCheck is transmitting an FVC test to the Printer/Charger.

SEND MVV The PneumoCheck is transmitting an MVV test to the Printer/Charger.

STEADY	Don't move the PneumoCheck. It is referencing zero flow in order to establish a baseline.
TEST.MODE	Entrance into the test mode of the PneumoCheck. This mode is used for testing and documenting calibration.
TEMP.LIM	The temperature range limit has been exceeded. Allow PneumoCheck to return to operating range (15 to 35°C) or (59 to 95°F). Blocked vents on Printer/Charger may cause this problem.
TOO SOON	The patient began exhaling before the instrument was ready. Repeat the test, waiting to hear the beep.
TRIM.LIM	The device cannot trim the baseline. This is usually due to an abrupt thermal change or a weak battery. Return instrument to an acceptable operating temperature range (15 to 35%) or (59 to 95°F) and fully charge before proceeding.

NOTE: Encountering either the TEMP.LIM or TRIM.LIM messages *during* normal *operation* may indicate a possible hardware failure. In this event, turn the PneumoCheck switch to OFF then ON again. Should this error persist, return your instrument to Welch Allyn.

TX FAIL	Transmission failure.
UNSTEADY	The PneumoCheck has detected airflow during STEADY portion of maneuver. Repeat test. If error persists, contact Welch Allyn.
VER X.X	The software version in your PneumoCheck spirometer.
VOL LIM	The volume during a maneuver has exceeded the PneumoCheck's capacity of 14 liters (minimum). Such an FVC volume is not possible from a human. Repeat the maneuver or recalibrate the PneumoCheck.

PNEUMOCHECK ERROR MESSAGES

The liquid crystal display will show the word ERROR and a number, e.g. "ERROR 2" when there is a problem with the instrument.

When an error message occurs, turn the PneumoCheck OFF and then ON again to reset the microprocessor. Then check the calibration and recalibrate if necessary. If the PneumoCheck continues to display ERROR, record the ERROR number and call your Welch Allyn representative.

PNEUMOCHECK TEST VALUES

FEVI x.xx The amount of air (in liters) that was exhaled during the first second of the FVC maneuver.

FVC x.xx The total amount of air (in liters) that was exhaled during the FVC maneuver.

MMEF x.xx The average flow (in liters per second) during the middle half of the FVC maneuver.

MVV xxx The total amount of air (in liters per minute) that was inhaled or exhaled during an MVV maneuver, normalized to one minute. Example: 30 liters of air over a 15 second period yields an MVV of 120 liters per minute. (30 liters/l 5 seconds x 60 seconds/ minute = 120 liters/minute)

PEF x.xx The highest instantaneous flow (in liters per second) during an FVC maneuver.

RATE xxx The number of breaths (per minute) taken during the timed MVV maneuver normalized to one minute.

RATIO xx The ratio of FEVI/FVC expressed as a percentage.

TIME xx.x The duration (in seconds) of the MVV maneuver.

APPENDIX B
MANEUVER QUALITY MESSAGES

BADSTART More than 5% or 0.1 liters of exhalation occurred before the back extrapolated starting point (ATS specification,,). To correct this, the patient should blast out harder at the beginning of the maneuver.

BAD.STOP The flow stopped abruptly. To correct this, the patient should keep blowing longer until all air has been expelled.

COUGH The patient coughed during the maneuver, or flow was interrupted or uneven. Have the patient remove his or her dentures and/or advise the patient to refrain from coughing. Sometimes a glass of water will help.

GOOD CAL Each of the three calibration maneuvers was within 0.5% of the average. The existing calibration factor will be replaced with the calibration factor from this calibration.

GOOD FVC The effort was acceptable--one with no obvious faults.

GOOD MVV The effort was acceptable.

MATCH This test has an FVC and FEVI within 5% (or an MVV within 15%) of the existing BEST test.

NO MATCH This test has a lower FVC or FEV1 by at least 5% (or lower MVV by at least 15%) and will not replace the existing BEST test. To correct this, inhale more fully before exhaling, and blast out harder at the start (FVC), or pant more rapidly and deeply (MVV).

RETRYCAL	One or more of the calibration maneuvers differed from the average by more than 0.5%. The existing calibration factor is not updated.
TOO.SHORT	**During FVC:** the maneuver was less than 3 seconds long. The patient should inhale more deeply and exhale longer. **During MVV:** The maneuver was less than 6 seconds long. The patient should continue longer.
WEAK TRY	Low flow effort. To correct this, the patient should blast out harder.

APPENDIX C
PREDICTED NORMAL VALUES

THE IDEAL STUDY

In order to evaluate spirometric data, one must compare the data with values derived from a study of a large number of normal individuals. The ideal study would:

Include only persons with no respiratory symptoms or exposure to agents known to cause lung dysfunction such as smoking, air pollution, or occupational exposure to inhaled chemicals or dusts.

Include a large number of persons from all age groups and races with a diversity of body types.

Utilize equipment which measures the volume or flow rates with extreme precision.

Include persons who could perform acceptable maneuvers with good reproducibility.

PREDICTEDS AVAILABLE ON YOUR PNEUMOCHECK

While the ideal study does not exist, many studies are available, all of which have unique advantages and shortcomings. Unfortunately, universal agreement as to which studies should be used does not exist.

The PneumoCheck provides a selection of four studies:

Knudson, 1976[13]
Knudson, 1983[12]
Morris, Crapo, et al.[14]
European Community for Coal and Steel[16]

NOTE: Not all of these studies define the predicted values for all age groups. For example, the Morris[14] study does not define predicted values for female patients younger than 17 years of age. Please refer to the notes included with each study to determine the predicted values that will be provided by the printer when ages outside the study ranges have been selected. The PneumoCheck printer will provide predicreds for the following height range: 85-214 cm or 33-84 inches.

RACIAL DIFFERENCES

If the race switch on the front panel of the printer is set to 2, the calculated predicted values are computed as indicated in the tables on pp. 54-58. If the race setting is set to 1, the calculated predicted values are then multiplied by 0.85 (except for FEVi/FVC).

CALCULATING PREDICTED VALUES MANUALLY

The PneumoCheck Printer/Charger calculates predicted values automatically, and an asterisk is placed in the ABN column if the actual parameter falls below the lower limit of normal (LLN).

Manual calculations can be made using the procedure and tables which follow:

All predicted values (except as noted) are calculated using the formula:

Value = (FI x age) + (F2 x height) + constant

where the FI and F2 multipliers and the constant are taken from the appropriate table entry and height is in centimeters.

For example, using Knudson's 1983 tables, the predicted normal FVC for a 20 year old male who was 6'0" tall would be calculated as follows:

1. First convert the height to centimeters.

   height = 72" x 2.54 cm/inch = 182.9 cm

2. Next, find the table entries for a male 20 years old, and calculate the FVC.

   FVC = (0.0739 x 20 years) + (0.0590 x 182.9 cm) - 6.8865
   FVC = 1.478 + 10.79 - 6.8865 or
   FVC = 5.38 liters

This patient would have an abnormally low FVC if his actual FVC was less than the "lower limit of normal", which is calculated using the entry from the LLNF column as follows:

Lower Limit of Normal = Value x LLNF (for LLNF > 0) or
Lower Limit of Normal = Value + LLNF (for LLNF < 0)

For example, our 20 year old male would have a lower limit of normal for his FVC of :

Lower Limit = 5.38 x 0.798 = 4.29 liters

This means that if his actual FVC is lower than 4.29 liters, it is considered to be abnormally low. Conversely, if his actual FVC is larger than 4.29 liters, his FVC is considered to be in the normal range.

NORMAL VALUES - KNUDSON, 1983[12]

	F1 (AGE)	F2 (HEIGHT)	CONSTANT	LLNF
Male, 6-11 yrs				
FVC	0.0	0.0409	-3.3756	0.749
FEV1	0.0	0.0348	-2.8142	0.780
RATIO	0.0	-0.0813	100.4389	0.850
MMEF	0.0	0.0338	-2.3197	0.439
PEF	0.166	0.078	-8.06	-2.711
Male, 12-24 yrs				
FVC	0.0739	0.0590	-6.8865	0.798
FEV1	0.0636	0.0519	-6.1181	0.812
RATIO	0.0	-0.0813	100.4389	0.850
MMEF	0.0749	0.0539	-6.1990	0.588
PEF	0.166	0.078	-8.06	-2.711
Male, 25-39 yrs				
FVC	-0.0298	0.0844	-8.7818	0.811
FEV1	-0.0292	0.0665	-6.5147	0.791
RATIO	-0.105	0.0	86.6862	0.869
MMEF	-0.0363	0.0579	-4.5175	0.553
PEF	-0.035	0.094	-5.993	-3.408
Male, 40-84 yrs				
FVC	-0.0298	0.0844	-8.7818	0.734
FEV1	-0.0292	0.0665	-6.5147	0.772
RATIO	-0.105	0.0	86.6862	0.869
MMEF	-0.0363	0.0579	-4.5175	0.403
PEF	-0.035	0.094	-5.993	-3.408
Female, 6-10 yrs				
FVC	0.0	0.0430	-3.7486	0.730
FEV1	0.0	0.0336	-2.7578	0.730
RATIO	0.6655	-0.1909	109.9739	0.805
MMEF	0.0	0.0220	-0.8119	0.383
PEF	0.157	0.049	-3.916	-2.196

	F1 (AGE)	F2 (HEIGHT)	CONSTANT	LLNF
Female, 1 l-1 9 yrs				
FVC	0.0699	0.0416	-4.4470	0.749
FEVI	0.0694	0.0351	-3.7622	0.818
RATI O	0.6655	-0.1909	109.9739	0.805
MMEF	0.1275	0.0279	-2.8007	0.562
PEF	0.157	0.049	-3.916	-2.196
Female, 20-39 yrs				
FVC	-0.0169	0.0444	-3.1947	0.769
FEVI	-0.0190	0.0332	-1.8210	0.703
RATI O	-0.1896	-0.1852	121.6777	0.859
MMEF	-0.0309	0.0300	-0.4057	0.448
PEF	-0.025	0.049	-0.735	-2.632
Female, 40-69 yrs				
FVC	-0.0169	0.0444	-3.1947	0.752
FEV1	-0.0190	0.0332	-1.8210	0.779
RATI O	-0.1896	-0.1852	121.6777	0.859
MMEF	-0.0309	0.0300	-0.4057	0.592
PEF	-0.025	0.049	-0.735	-2.632
Female, 70-87 yrs				
FVC	-0.0296	0.0313	-0.1889	0.718
FEVI	-0.0397	0.0143	2.6539	0.726
RATI O	-0.1896	-0.1852	121.6777	0.859
MMEF	-0.0615	0.0000	6.3706	0.569
PEF	-0.025	0.049	-0.735	-2.632

NOTE: PEFvalues are obtained from Knudson,1976 as opposed to Knudson,l983.

NORMAL VALUES FOR KNUDSON, 1976[13]

	F1 (AGE)	F2 (HEIGHT)	CONSTANT	LLNF
Male, 8-24 yrs				
FVC	0.078	**0.050**	-5.508	-0.892
FEVI	0.045	**0.046**	-4.808	-0.858
RATIO	-0.140	**-0.087**	103.64	-11.02
MMEF	0.000	**0.059**	-5.334	-1.530
PEF	0.166	**0.078**	-8.060	-2.711
Male, 25-78 **yrs**				
FVC	-0.029	**0.065**	-5.459	-0.986
FEVI	-0.027	**0.052**	-4.203	-0.887
RATIO	-0.140	**-0.087**	103.64	-11.02
MMEF	-0.031	**0.045**	-1.864	-1.901
PEF	-0.035	**0.094**	-5.993	-3.408
Female, 8-19 yrs				
FVC	0.092	**0.033**	-3.469	-0.820
FEVI	0.085	**0.027**	-2.703	-0.692
RATIO	-0.109	-0.111	107.38	-12.57
MMEF	0.121	0.025	-1.893	-1.410
PEF	0.157	0.049	-3.916	-2.196
Female, 20-78 yrs				
FVC	-0.022	0.037	-1.774	-0.851
FEVI	-0.021	0.027	-0.794	-0.712
RATIO	-0.109	-0.111	107.38	-12.57
MMEF	-0.024	0.021	1.171	-1.629
PEF	-0.025	0.049	-0.735	-2.632

NOTE: The printer will provide predicteds for males aged 6-7 and 79-84 and for females aged 6-7 and 79-87. These predicted values are from the Knudson, 1983 study.

NORMAL VALUES FOR MORRIS, CRAP0 et al., 1981 [14]

	F1 (AGE)	F2 (HEIGHT)	CONSTANT	LLNF
Male, 15-91 yrs				
FVC	-0.0214	0.0600	-4.650	-1.115
FEVI	-0.0244	0.0414	-2.190	-0.842
RATIO	-0.152	-0.1300	110.49	-8.280
MMEF	-0.0380	0.0204	2.133	-1.666
Female, 17-84 yrs				
FVC	-0.0216	0.0491	-3.590	-0.676
FEVI	-0.0255	0.0342	-1.578	-0.561
RATIO	-0.252	-0.2020	126.58	-9.060
MMEF	-0.0460	0.0154	2.683	-1.363

NOTE: Peak flow values (PEF) are always calculated using the coefficients from Knudson, 1976. The printer will provide predicteds for males aged 6-l 4 years and for females aged 6-l 6 years. These predicted values are from the Knudson, 1983 study.

NORMAL VALUES FOR EUROPEAN COMMUNITY FOR COAL AND STEEL [16]

	F1 (AGE)	F2 (HEIGHT)	CONSTANT	LLNF
Male, 25-70 yrs				
FVC	-0.026	0.0576	-4.34	-1 .000
FEVI	-0.029	0.0430	-2.49	-0.836
RATIO				-11.76
MMEF	-0.043	0.0194	2.70	-1.706
PEF	-0.043	0.0614	0.15	-1.984
Female, 25-70 yrs				
FVC	-0.026	0.0443	-2.89	-0.705
FEVI	-0.025	0.0395	-2.60	-0.623
RATIO				-10.68
MMEF	-0.034	0.0125	2.92	-1.394
PEF	-0.030	0.0550	-1 .II	-1.476

NOTE: Per Quanjer, 1983[16], male and female values are extrapolated to age 87 by the printer and values provided for subjects aged 18-24 are the same as those provided for a 25 year old subject. For subjects 6-I 7 years of age PEF values are from Knudson, 1976, and all others are from Knudson, 1983.

*Ratio values are calculated by dividing the predicted FEVI by the predicted FVC.

COEFFICIENTS FOR MVV's[11]

	F1 (AGE)	F2 (HEIGHT)	CONSTANT	LLNF
Female, 6-19 yrs				
MVV	0.0	1.276	-100	-18
Female, 20-71 yrs				
MVV	-0.82	0.91	-11	-16
Male, 6-19 yrs				
MVV	0.0	1.276	-100	-18
Male, 20-80 yrs				
MVV	-1.26	1.34	-21	-30

APPENDIX D
TECHNICAL SPECIFICATIONS

The PneumoCheck Spirometer complies with the recommendations of the American Thoracic Society[19] as they apply to both the spirometer and the printer/charger.

PNEUMOCHECK

Power Consumption:	0.5 to 20 ma at 7.2 VDC
Charging Rate:	12 ma DC
Low Battery Threshold:	6.0 - 6.3 VDC
Flow Resolution:	16 ml/sec
Flow Capacity:	14 liters/sec, BTPS
Volume Resolution:	0.45 ml
Volume Capacity:	14 liters, BTPS
Flow Sampling Rate:	2,304 samples/sec
Maneuver Sampling Time:	25 sec
Active Maneuver Time (FVC):	15 sec
Temperature Drift of Gain:	Less than 1% per 5° C
Operating Temperature:	15 to 35° C (59 to 95° F)
	All Specifications apply over this temperature range
Storage Temperature:	-20 to 40° C (-4 to 104° F)
"Zero Time" Determination (FEV):	Back extrapolation
Anesthetics:	Not suitable for use in presence of flammable anesthetics.

PRINTER/CHARGER

Operating Voltage Range:	100/l 20 ±1 0% VAC, 50/60 Hz
Power Consumption:	60 Watts max.
Printer Paper:	Thermal type, 4.36" wide (110 mm) with core
Operating Temperature:	15 to 35° C (59 to 95° F)
Storage Temperature:	-20 to +40° C (-4 to 104°F)
Printed Flow Rate Range (Flow/Volume Curve):	0 - 14 l/s
Printed Volume Range (Flow/Volume and Volume/Time Curves):	0 - 8 liters
Printed Time Range (Volume/Time Curve):	0 - 7 s
Printer Predicted Options:	Knudson, 1983; Knudson, 1976; Morris, Crapo et al.; European Community for Coal and Steel
Printer Format Options:	Short Form/Long Form; Flow/Volume Plot; Volume/Time Plot
Scale Factors:	Time = 20 mm/sec Volume = 10 mm/L Flow = 5 mm/L/s

STANDARDS COMPLIANCE

This instrument complies with the following standards, based on the most recent revision available at the time of design.

ATS	Design meets 1987 ATS recommendations,,
OSHA	1910.1043
UL	Listed (UL 544)
CSA	Certified (C22.2 No. 125)
IEC	601-l (Handle: Type B applied part; Printer: Class 1 equipment)

APPENDIX E
GLOSSARY

ATS American Thoracic Society. The ATS is a scientific organization whose members are active in pulmonary research and the care of patients with lung diseases. The ATS is interested in promoting the accurate and appropriate use of spirometers and has recommended a set of standards for spirometers: "ATS Statement on Standardization of Spirometry 1987"[19]. The public relations branch of the ATS is called the American Lung Association.

Back Extrapolation The method recommended by the ATS to determine "time-zero" when measuring the **FEVI .** Refer to ATS standards for a full explanation of this method.

BEV Back Extrapolated Volume. The amount of air exhaled by a subject before the "time-zero," which is determined by the method of back extrapolation. In practice, a large BEV results from a slow or hesitating start at the beginning of a forced exhalation maneuver.

BTPS Factor Body Temperature and Pressure, Saturated. A number used to express all spirometry results uniformly at body temperature and pressure, fully saturated with water.

Calibration Syringe A large syringe, also known as a "super syringe", which is used to check the calibration of a spirometer or to recalibrate it. The ATS recommends that it be at least 3.0 liters in size for use in checking spirometers.

Demographic Data Information about a patient including age, height, sex and race necessary to predict normal values for that patient.

Dyspnea Sensation of breathlessness or shortness of breath.

FEF 2575% (MMEF)	Forced Expiratory Flow between the 25% and 75% volume points or Mean Mid Expiratory Flow, expressed as average flow during the middle half of the maneuver.
FEFmax	See PEF
FEVI	Forced Expiratory Volume (timed) in liters. The volume of air that is exhaled during the first second of an FVC maneuver. It is decreased by an airflow limitation or obstruction of the patient's airways.
FEVI - Best	The largest Forced Expiratory Volume in liters of any maneuver done by the patient. It usually is from the best maneuver, but may not be from the same maneuver as the best FVC.
FEVI /FVC%	The ratio of FEVI to FVC, expressed as a percentage.
FVC	Forced Vital Capacity expressed in liters. The amount of air that can be exhaled during a rapid forced exhalation. It may be reduced due to disorders causing lung restriction, airflow limitation causing air trapping, or a poor inspiratory effort by the patient during testing.
FVC - Best	The largest Forced Vital Capacity of any maneuver done by the patient. It usually comes from the best maneuver, but may not come from the same maneuver as the best FEVI.
Flow-Volume Curve	The graph obtained from a forced exhalation maneuver plotted with flow on the vertical axis and volume on the horizontal axis.
MMEF	See FEF 25-75%.

MVV	Maximal Voluntary Ventilation, expressed in liters per minute. The largest volume of air inhaled or exhaled over a timed period, typically 12 to 15 seconds, which is then extrapolated to one minute. The maneuver should imitate the rapid breathing of strenuous exercise.
PEF	Peak Expiratory Flow Rate in liters per second. It is the highest instantaneous flow during an FVC maneuver. It is an index of patient effort.
Ratio	See FEVl /FVC%.
Rate	The breathing rate during an MVV maneuver, expressed in breaths per minute.
Volume-Time Curve	The traditional spirogram obtained from a volume spirometer, with time increasing on the horizontal axis to the right and volume increasing upwards on the vertical axis.

APPENDIX F
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This manual applies to:
- PneumoCheck software version 3.2 through 3.4
- Printer/Charger software version 3.2

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